

EXHIBIT B-7

WDO
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Subject: CAPA130022 – Defective percentage justification

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Time frame selection

The analysis of percentage defective rate is realized on data from the November 22th, 2012 to January 30th, 2013. Start point is the date of the first NCR opened for this problem. End point is the date of origination of the CAPA to fix this problem. (An updated rationale could be providing when necessary. Example: at the review of the Risk document PFMEA)

Number of defective / non defective parts

Non defective parts - During the time frame, 65 batches of TVT products were manufactured.

(Data extracted from updated Excel file TAM: L:\UNJCHNE\DEPARTEMENT\ETHICON\SHARED\METRICS\Requests\WO_Ethicon_TAM.xls)

Defective parts - During this time frame, 3 NCR were opened (Even if one new NCR was open between 01/30/2013 and 16/30/2013, it is not include in this calculation).

NCR	Date	Number of parts impact*	Number of batches impact*
*Data extracted from NCR files			
12-10293	22.nov.12	0 defective part. Particles were found directly in the box.	2 batches reworked on 4 batches controlled
12-10960	13.dec.12	4 defective parts found before stop control and rework the entire batch. (Same operation for previous and following batches)	2 batches reworked on 4 batches controlled
13-00712	25.janv.13	1 defective part found before stop control and rework the entire batch. (Same operation for previous and following batches)	3 batches reworked on 5 batches controlled
		5 parts were detected as defective but not 100% of parts were controlled. As at least 1 part detected as defective a 100% rework was conducted.	7 batches were reworked as affected batches

Using a calculation by defective batches rather by defective parts is a choice more critical but also more representative. Indeed there are an unknown number of parts impacted on each batch.

Conclusion

The defective percentage use for the definition of this CAPA will be: 7 impacted batches on 65 manufactured batches between the November 22th, 2012 and January 30th, 2013.